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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,412	03/15/2002	Anna-Stina Hoglund	HOGL3001/REF	8514
23364	7590	12/02/2004	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,412	HOGLUND ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 September 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,10-12,14-16 and 18-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4-9,13 and 17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 3/15/02.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Claims 1-20 are pending. Claims 2-3, 10-12, 14-17 and 18-20 are withdrawn. Claims 1, 4-9, 13 and 17 are examined.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1, 4-9, 13, 17 in the reply filed on 9/13/2004 is acknowledged. The traversal is on the ground(s) that the prior art cited did not teach the special technical feature of a truncated protein. This is not found persuasive because the cited art does teach a truncated protein on page 23 lines 13-22 teach the truncated polypeptide encoded by nucleotides 211-1321 of *crtO* from the alga *Haematococcus pluvialis* operably linked to the promoter and transit peptide of the *PDS* gene. Further, Applicant is invited to inspect SEQ ID NO: 3 on page 44 of the prior art reference that teaches the protein sequence encoded by SEQ ID NO: 1, wherein the protein sequence encoded by nucleotides 211-1321 is missing the first 15 amino acids of the native protein sequence, and thus the protein used to transform the plant is truncated.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann V. *et al.* WO 98/18910 published 05/07/1999.

The claims are broadly drawn to a transformed plant cell of any type from any species comprising a DNA construct having operably linked any promoter capable of directing any level of expression in a seed, any chloroplast transit peptide, and any 5'-truncated beta-carotene C-4-oxygenase gene from *Haematococcus pluvialis*, wherein the transformed plant cell expresses a xanthophylls such as a canthaxanthin, astaxanthin or an astaxanthin ester.

The reference teaches tobacco transformed with a DNA construct comprising a *pds* promoter and DNA encoding a chloroplast transit peptide from tomato operably linked to a truncated *crtO* gene encoding a beta-carotene C-4-oxygenase from the alga *Haematococcus pluvialis* (see page 23 Kajiwara *et al.* 1995; GeneBank Accession No. D45881 and also see SEQ ID NO: 3 on page 44 of the prior art reference that teaches the protein sequence encoded by SEQ ID NO: 1, wherein the protein sequence encoded by nucleotides 211-1321 is missing the first 15 amino acids of the native protein sequence) and a transcription termination region on pages 23 and page 39 in lines 16-29; and a transformed tobacco plant producing astaxanthin (page 41 Table 5), wherein the production of esterified astaxanthin is inherent because plants comprise native acyl transferases required for the process of esterifying astaxanthin (see specification page 4 lines 1-7), and thus the reference teaches all the limitations of Claims 1, 6, 8 and 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-9, 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann *et al.* WO 98/18910 published 05/07/1999 in view of Shewmaker C. WO 99/07867 published 02/18/1999 and in view of Applicant's admission of the prior art on page 4 of the specification.

The claims are broadly drawn to a transformed plant cell of any type from any species comprising a DNA construct having operably linked any promoter capable of directing any level of expression in a seed, any chloroplast transit peptide, and any 5'-truncated beta-carotene C-4-oxygenase gene from *Haematococcus pluvialis*.

Mann teaches tobacco transformed with a DNA construct comprising a *pds* promoter and DNA encoding a chloroplast transit peptide from tomato operably linked to a truncated *crtO* gene encoding a beta-carotene C-4-oxygenase from the alga *Haematococcus pluvialis* (see page 23 Kajiwara *et al.* 1995; GeneBank Accession No. D45881 and also see SEQ ID NO: 3 on page 44 of the prior art reference that teaches the protein sequence encoded by SEQ ID NO: 1, wherein the protein sequence encoded by nucleotides 211-1321 is missing the first 15 amino acids of the native protein sequence) and a transcription termination region on page 23; and a transformed tobacco plant producing astaxanthin (page 41 Table 5).

Mann does not teach a seed specific NapA napin promoter (GeneBank Accession No. J02798), an *Arabidopsis RBCS1a* transit peptide (GeneBank Accession No. X13611), or transformed rape seed having an increased amount of canthaxanthin.

Shewmaker teaches *Brassica napus* (i.e. rape) transformed with a napin promoter/SSU transit peptide leader sequence fused to a *crtB* gene (page 32 lines20-27) and an increase of the production of castaxanthin in *Brassica* seeds transformed with *crtB* and *crtW*, and that the *crtO*

gene encoding a beta-carotene C-4-oxygenase is useful for the production of canthaxanthin when expressed alone and useful for the production of astaxanthin when expressed with *crtW* (page 13 lines 19-23).

Applicant's admission of the prior art teaches a seed specific NapA napin promoter (GeneBank Accession No. J02798) and an *Arabidopsis RBCS1a* chloroplast transit peptide (GeneBank Accession No. X13611).

It would have been obvious to modify the invention of Mann by inserting the *crtO* gene encoding a truncated beta-carotene C-4-oxygenase taught by Mann into the napin promoter/SSU transit peptide construct, either additionally comprising a *crtW* gene or not, for transforming *Brassica* plants (i.e. rape) to increase the canthaxanthin, astaxanthin, or astaxanthin ester fraction of an oilseed plant cell such as rape as taught by Shewmaker. One of skill in the art would have been motivated by the teachings of Mann that a truncated *crtO* gene from *H. pluvialis* can when transformed into a plant cell will increase the astaxanthin production; and by the teachings of Shewmaker that a napin promoter/SSU transit peptide construct comprising a *crtO* gene, when expressed either alone or in combination with a *crtW* gene, would be a valuable tool for engineering increases in canthaxanthin and astaxanthin or astaxanthin esters in oilseed plant cells, such as rape (i.e. *Brassica napus*) generally deficient in canthaxanthin and astaxanthin production; and that one of skill in the art would have a reasonable expectation of success of increasing canthaxanthin, astaxanthin or astaxanthin ester production in an oilseed plant cell given the success of both Mann and Shewmaker of engineering increases in astaxanthin and canthaxanthin in plant cells respectively and given that plants have endogenous acyl transferase activity; and that the substitution of the prior art napin promoter (page 4 of specification,

GeneBank Accession No. J02798) and prior art SSU transit peptide sequence (page 4 of specification, GeneBank Accession No. X13611) for the napin promoter and SSU transit peptide sequences taught by Shewmaker are an obvious substitution absent any evidence of criticality; and when combined together with the *crtO* gene affirmed in Applicant's specification as GeneBank Accession No. D45881 also taught by Mann, render SEQ ID NO: 1 of Claim 4 obvious over the prior art.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Kallis Ph.D.
November 26, 2004